



## General

### Guideline Title

Clinical practice guidelines for surveillance colonoscopy — in adenoma follow-up; following curative resection of colorectal cancer; and for cancer surveillance in inflammatory bowel disease.

### Bibliographic Source(s)

Cancer Council Australia Colonoscopy Surveillance Working Party. Clinical practice guidelines for surveillance colonoscopy “in adenoma follow-up; following curative resection of colorectal cancer; and for cancer surveillance in inflammatory bowel disease. Sydney (Australia): Cancer Council Australia; 2011 Dec. 144 p. [420 references]

### Guideline Status

This is the current release of the guideline.

## Recommendations

### Major Recommendations

*Note from the National Guideline Clearinghouse (NGC):* Evidence summaries, levels of evidence, and references associated with the recommendations can be found in the original guideline document.

Grades of recommendation (A-D) are defined at the end of the "Major Recommendations" field.

#### Management of Epithelial Polyps: Colonoscopic Surveillance after Polypectomy

##### Adenomas and Risk of Developing Colorectal Cancer (CRC)

Practice point:

- Determination of risks for patients with adenomas must clearly distinguish between:
  1. Variables that relate to the likelihood of any particular adenoma having a malignant focus and
  2. Variables that relate to patient, pathological, and epidemiological characteristics which predict a risk of future (metachronous) adenomas and cancers.
- Patients whose only polyps are small, pale, distal, hyperplastic polyps require no colonoscopic follow-up.

#### *Identifying the Risk of Metachronous Neoplasia after Removal of Adenomas*

#### Location of Adenomas and Cancer: Protection against Right Sided Cancer in Adenoma Follow-up

Practice point:

- Proximal location of adenomas may be a risk factor for metachronous neoplasia. The extent to which this is driven by the difficulty of detecting proximal polyps, because of their flat and unobtrusive nature (i.e., sessile serrated polyps), poor bowel preparation, and anatomical blind spots in the right colon, is unclear. For these reasons the right colon deserves particularly careful scrutiny at colonoscopy.

#### Models for Risk Index

Practice point:

- Because of the complexity of multivariate analyses equations to predict individual patient risk of metachronous polyps, their use currently is difficult to apply to day to day practice.

#### Polypectomy

##### *General Considerations Relating to Polypectomy*

Practice point:

- All polyps should be considered for removal. Diminutive polyps (5 mm or less) may be too numerous to be cleared completely. In patients with multiple small polyps, a sample of at least three should be taken for histological study. However, if a syndromic diagnosis is under consideration, then sampling of many more polyps is important, to guide decisions on which gene should be subjected to mutational analysis.

##### *Tattooing Polypectomy Sites*

Practice point:

- Tattooing any polyp site where there is a possibility that surgical resection will be needed is important at the primary colonoscopy if at all possible, or very soon after with a second procedure. This is necessary even for conventional surgery, as the site of polypectomy may well be impalpable, but particularly important where follow-up treatment may be laparoscopic, as the surgeon has no capacity to palpate the area.

#### Malignant Polyps

Practice point:

- In general, malignant polyps which:
  1. Have a clear margin of excision
  2. Are well or moderately differentiated
  3. Lack lymphatic or venous invasion
  4. Are endoscopically assessed as totally removed can be managed without subsequent surgical resection. However, the decision needs to be individualized with respect to the particular histological and endoscopic features and the patient's age and co-morbidities.

#### Follow-up Surveillance for Adenomas

##### *Quality of Colonoscopy*

Practice point:

- High quality colonoscopy is critically important for good practice and patient safety. Adenoma detection rates should be monitored, though they will be influenced by patient mix (e.g., age profile, indications). Adenoma detection rates within the National Bowel Cancer Screening Program provide a sound basis for benchmarking.

##### *Approach to Adenoma Follow-up in Surveillance*

Practice point:

- Colonoscopy surveillance intervals should be planned when the colonoscopist is satisfied that the colon has been completely cleared of polyps and the polyp histology is known.

##### *Follow-up for Patients with Low Risk Adenomas*

#### Recommendations:

- In follow-up of patients with one or two small (<10 mm) tubular adenomas, the first surveillance colonoscopy should be performed at five years. (Grade B)
- If that colonoscopy is normal, the individual is considered to be at average risk for metachronous disease. Options for subsequent surveillance are ten-yearly colonoscopy, or faecal occult blood test at least every two years. (Grade B)

#### Practice points:

- Low risk adenomas are those which lack advanced features, namely three or more adenomas at one colonoscopy, adenomas 10 mm or more in size, tubulovillous or villous histology or high grade dysplasia/cancer.
- There is no conclusive evidence that one or two small tubular adenomas constitute more than average risk for metachronous advanced adenomas or cancer.

#### *Follow-up for Patients with High Risk Adenomas*

##### Recommendation:

- Surveillance colonoscopy should take place at three yearly intervals for patients with high risk adenomas (three or more adenomas,  $\geq 10$  mm, or with tubulovillous, or villous histology, or high grade dysplasia). (Grade A)

#### *Follow-up of Patients with Sessile Adenomas and Laterally Spreading Adenomas*

##### Recommendation:

- If large and sessile adenomas are removed piecemeal, follow-up colonoscopy should be at three to six months and again at twelve months to ensure complete removal. If removal is complete, subsequent surveillance should then be based on histological findings, size, and number of other adenomas (as set out in "Follow-up for Patients with Low Risk Adenomas" and "Follow-up for Patients with High Risk Adenomas," above). (Grade B)

#### *Follow-up Following Resection of Serrated Adenomas and Sessile Serrated Adenomas*

##### Practice point:

- At present there is not enough evidence to differentiate follow-up protocols for sessile serrated adenomas from standard adenoma follow-up guidelines. Follow-up should be determined as for adenomatous polyps, taking into account parameters such as, polyp size, number, and presence of high grade dysplasia.

#### *Follow-up for Patients with Multiple Adenomas*

##### Recommendation:

- As multiplicity of adenomas is a strong determinant of risk of metachronous advanced and non-advanced neoplasia, follow-up should be at twelve months for those with five or more adenomas and, because the likelihood of missed synchronous polyps being present, sooner in those with ten or more adenomas.
- If a polyposis syndrome accounts for the findings, follow-up colonoscopy should be within one year for patients with five or more adenomas at one examination.  
(Grade B)

##### Practice point:

- Familial adenomatous polyposis (FAP) or *MYH* associated polyposis should be considered with as few as ten adenomas; referral to a familial cancer clinic is advisable.

#### *Interaction of Age and Family History of Colorectal Neoplasia*

##### Recommendation:

- Family history should be considered separately when planning colonoscopy surveillance. Intervals should be predominantly determined by the adenoma characteristics, unless a syndromic risk mandates more frequent surveillance. (Grade B)

## *Follow-up Based on Two or More Examinations*

### Recommendation:

- If advanced adenomas are found during subsequent surveillance, maintaining a three yearly schedule is prudent, but the choice should be individualised. The interval can be lengthened if advanced adenomas are not found. (Grade B)

### Practice point:

- Endoscopists, therefore, should be encouraged to assess not only the current colonoscopy findings, but those of any previous colonoscopies.

## Hyperplastic Polyposis

### Practice points:

- Risk of cancer in hyperplastic polyposis is still being defined; however, there is sufficient evidence to identify these patients as being at high risk. Colonoscopy, with the aim of complete polyp removal, including the right sided sessile serrated polyps, should be the aim. Risks of polypectomy, notable because of the number and sessile nature of these polyps, should be explained.
- Surgery is an acceptable alternative in patients with well defined hyperplastic polyposis.

## The Role of Surveillance Colonoscopy after Curative Resection for CRC

### Role of Pre- or Peri-operative Colonoscopy in CRC Patients

#### Recommendations:

- A perioperative colonoscopy should be attempted in all patients with a newly diagnosed CRC. (Grade B)
- Colonoscopy should be performed three to six months after resection for patients with obstructive CRC in whom a complete perioperative colonoscopy was not performed and in whom there is residual colon proximal to the obstructing cancer. (Grade B)

### Which Patients Should Be Followed up with Surveillance Colonoscopy?

#### *Patient Groups at Very High Risk for Metachronous Neoplasia following Resection for CRC*

#### Practice points:

- Patients with proved Lynch syndrome (hereditary non-polyposis CRC [HNPCC]), should continue to have annual surveillance colonoscopy performed post-operatively because of the apparent rapid progression of neoplasia from adenoma to carcinoma.
- Surveillance of the residual colonic mucosa in patients with cancer in FAP should follow recommendations in Chapter 7 of the Clinical Practice Guidelines for the Prevention, Early Detection, and Management of Colorectal Cancer, 2nd edition, 2005.
- Patients including those:
  - i. Whose initial diagnosis was made younger than 40 years of age
  - ii. With probable or possible HNPCC (i.e., patients whose tumours are microsatellite instability [MSI]-high and less than 50 years old at time of initial cancer diagnosis but not proved by genetic testing to have HNPCC)
  - iii. With hyperplastic polyposis and *BRAF* mutation and
  - iv. With multiple synchronous cancers or advanced adenomas at initial diagnosis should be considered following surgery to continuing with more frequent surveillance than would otherwise be recommended (e.g., initial post-operative colonoscopy at one year and then annually, second-yearly, or third-yearly).

### Intervals for Surveillance Colonoscopy following Resection for CRC

#### Recommendations:

- Colonoscopy should be performed one year after the resection of a sporadic cancer, unless a complete post-operative colonoscopy has been performed sooner. (Grade B)
- If the peri-operative colonoscopy or the colonoscopy performed at one year reveals advanced adenoma, then the interval before the next colonoscopy should be three years. (Grade C)
- If the colonoscopy performed at one year is normal or identifies no advanced adenomas, then the interval before the next colonoscopy should be five years. (Grade C)

Practice point:

- Patients undergoing either local excision (including transanal endoscopic microsurgery) of rectal cancer or advanced adenomas or ultra-low anterior resection for rectal cancer should be considered for periodic examination of the rectum at six monthly intervals for two or three years using either digital rectal examination, rigid proctoscopy, flexible proctoscopy, and/or rectal endoscopic ultrasound. These examinations are considered to be independent of the colonoscopic examination schedule described above.

### Colonoscopic Surveillance and Management of Dysplasia in Inflammatory Bowel Disease (IBD)

#### Efficacy of Colonoscopic Surveillance in IBD

Recommendation:

- Colonoscopic surveillance is recommended in high risk patients with ulcerative colitis to reduce cancer-related mortality. (Grade C)

Practice point:

- Although evidence for colonoscopic surveillance in Crohn's disease is limited, experts recommend it be considered in at risk patients.

#### How Is Surveillance Practised, and Can It Be Improved?

##### *Starting Time for Surveillance*

Recommendations:

- Patients with ulcerative colitis extending beyond the sigmoid colon and individuals with Crohn's colitis that involves more than one-third of colon should commence surveillance no later than eight years after onset of symptoms. (Grade C)
- If primary sclerosing cholangitis is detected before this time, surveillance should commence at the time of its diagnosis. (Grade C)
- Patients with a strong personal family history of CRC should start surveillance earlier. (Grade C)

#### Optimal Surveillance Intervals

Practice points:

- Annual colonoscopic surveillance is recommended for patients with ulcerative colitis extending proximal to the sigmoid colon or patients with Crohn's colitis affecting more than one third of the colon and with one or more of the following risk factors:
  - Active disease
  - Primary sclerosing cholangitis
  - Family history of CRC in first degree relative <50 years old
  - Colonic stricture, patients with multiple inflammatory polyps or shortened colon
  - Previous dysplasia
- Three yearly colonoscopy is recommended for patients with:
  - Inactive ulcerative colitis extending proximal to the sigmoid colon without any of the above risk factors
  - Patients with Crohn's colitis affecting more than one third of the colon without any of the above risk factors
  - IBD patients with a family history of CRC in a first degree relative >50 years old
- Five yearly colonoscopy recommended for patients in whom two previous colonoscopies that were macroscopically and histologically normal.

#### Optimal Colonoscopic Protocol

Recommendations:

- If available, the use of chromoendoscopy/dye spraying where targeted biopsies are obtained from visibly abnormal lesions or strictures is the preferred means to conduct colonoscopic surveillance in IBD. This is especially true for patients at high risk of CRC. (Grade C)
- If chromoendoscopy is unavailable, or if an endoscopist lacks sufficient expertise with this technique, or if the presence of inflammation interferes with the interpretation of chromoendoscopy, an acceptable alternative practice is using standard white light endoscopy with random non-targeted biopsies from each colonic segment and from raised lesions. (Grade D)

Practice point:

- When chromoendoscopy is used, random biopsies are required from each colonic segment to establish histological extent and severity of

disease. More intensive mucosal sampling from each colonic segment is indicated in patients with a suspicious visible lesion or in situations where chromoendoscopic interpretation is compromised by factors such as active inflammation, inflammatory polyps, or poor bowel preparation.

#### Surveillance Protocol Practised in Crohn's Disease, Indeterminate Colitis, and Patients with Ileo-anal Pouches

##### Recommendations:

- Based on cancer risk, it is recommended that similar colonoscopic surveillance be undertaken for Crohn's colitis as in ulcerative colitis of equivalent extent, even though supporting evidence is sparse. (Grade D)
- Specific areas where surveillance is required in Crohn's disease are patients with colonic strictures or complicated anorectal disease. (Grade D)

#### Management of Dysplasia

##### *Elevated Dysplastic Lesions*

##### Recommendations:

- Raised lesions containing dysplasia may be treated endoscopically provided the entire lesion is removed and there is no dysplasia in flat mucosa elsewhere in the colon. (Grade D)
- If a raised dysplastic lesion cannot be completely removed, or if there is dysplasia elsewhere in the colon, surgical intervention is strongly recommended. (Grade D)

##### *High Grade Dysplasia in Flat Mucosa*

##### Recommendation:

- High grade dysplasia in flat mucosa is a strong risk factor for established or imminent carcinoma, and colectomy is usually recommended. (Grade B)

##### *Low Grade Dysplasia in Flat Mucosa*

##### Recommendations:

- Multifocal low grade dysplasia is associated with a sufficiently high risk of future cancer that colectomy is usually recommended. Patients who elect to avoid surgery require follow up surveillance at three months, preferably with chromoendoscopy, and if this examination is normal, annually. (Grade C)
- Unifocal low grade dysplasia may be followed by ongoing surveillance at six months, and if this examination is normal, annually. (Grade C)

##### *Indefinite Dysplasia in Flat Mucosa*

##### Recommendation:

- Indefinite dysplasia in flat mucosa does not require surgery, but follow-up colonoscopic surveillance is justified, preferably with chromoendoscopy, at more frequent intervals. (Grade B)

#### Psychosocial Aspects of Surveillance Colonoscopy after CRC Resection, Polyps, and in IBD

##### Amelioration of Anxiety in Relation to Colonoscopy

##### Recommendation:

- Pre-colonoscopy advice to patients by means of educational material, video, and clinical explanation can assist in improving patient experience with the procedure and in reducing anxiety. (Grade C)

##### Music as an Aid to Improving Comfort of Colonoscopy

##### Recommendation:

- Music provided to patients during colonoscopy may reduce their discomfort. (Grade C)

#### Elements of Clinical Care Available for Patients Undergoing Colonoscopy

Practice point:

- Controversy continues with regard to choice of drugs for sedation and monitoring patients during colonoscopy.

#### Socioeconomic Factors - Aspects That May Impact on Surveillance Colonoscopy Following Adenoma Detection or Curative Resection for CRC and in the Setting of Dysplasia Surveillance in IBD

Impact Made by Socioeconomic Factors in the Three Treatment Groups undergoing Surveillance Colonoscopy

*Socioeconomic Status Post Curative Resection of CRC*

Recommendation:

- Clinicians may assist in improving survival outcomes in curative resection for CRC patients who are socioeconomically or otherwise disadvantaged by expediting their access to optimal clinical care. (Grade B)

Definitions:

Grades of Recommendation

Grade of Recommendation	Description
A	Body of evidence can be trusted to guide practice.
B	Body of evidence can be trusted to guide practice in most situations.
C	Body of evidence provides some support for recommendations but care should be taken in its application.
D	Body of evidence is weak and recommendation must be applied with caution.

Practice Point: When no Level I or II evidence was available but there was consensus among the working party members, recommended best practice points have been provided, and can be identified throughout the original guideline with the following: Practice Point (PP).

## Clinical Algorithm(s)

The following algorithms are available from the [Cancer Council Australia Web site](#) :

- Algorithm for Colonoscopic Surveillance Intervals – Adenomas
- Algorithm for Colonoscopic Surveillance Intervals – Following Surgery for Colorectal Cancer
- Algorithm for Colorectal Cancer Screening – Family History

## Scope

### Disease/Condition(s)

- Adenoma of the colon (adenomatous polyps)
- Colorectal cancer
- Inflammatory bowel disease (Crohn's disease and ulcerative colitis)

## Guideline Category

Evaluation

Management

Prevention

Risk Assessment

## Clinical Specialty

Colon and Rectal Surgery

Family Practice

Gastroenterology

Internal Medicine

Oncology

Preventive Medicine

## Intended Users

Advanced Practice Nurses

Health Care Providers

Physician Assistants

Physicians

## Guideline Objective(s)

- To update (and substantially expand) several small sections of the Australian Cancer Network Colorectal Cancer 2005 Clinical Practice Guidelines for the Prevention, Early Detection, and Management of Colorectal Cancer
- To assist those involved in the Australian healthcare system in making decisions about the timing of surveillance colonoscopy, namely referring general practitioners and colonoscopists, with the intention of reducing the incidence of and mortality from colorectal cancer

## Target Population

Patients known to be at above-average risk for colorectal cancer (CRC) development (i.e., patients who have already had adenomatous polyps removed or surgery for CRC, and patients with inflammatory bowel disease)

## Interventions and Practices Considered

1. Management of epithelial polyps: colonoscopic surveillance after polypectomy
  - Determination of risk for colorectal cancer (CRC)
  - Considerations related to polypectomy
  - Follow-up intervals
2. Surveillance colonoscopy after curative resection for CRC
  - Pre or peri-operative colonoscopy
  - Determination of risk levels for recurrence
  - Surveillance intervals
3. Colonoscopic surveillance (determination of optimal intervals) and management of dysplasia in inflammatory bowel disease
4. Management of anxiety and discomfort before and during colonoscopy

## Major Outcomes Considered

- Risk of adenomas, metachronous neoplasia including cancer, malignancy, synchronous adenomatous polyps or cancer, and second metachronous colorectal cancer (CRC)
- Rates of detection of adenomas, metachronous neoplasia including cancer, malignancy, synchronous adenomatous polyps or cancer, and second metachronous CRC
- Timing of cancer development or cancer recurrence
- Predictive value of colonoscopy
- Effectiveness of colonoscopy for CRC prevention
- Incidence of CRC
- Survival, including cancer-related, 5-year, and overall survival
- Mortality, including cancer-related mortality
- Levels of anxiety
- Levels of pain
- Need for sedation
- Cost-effectiveness of colonoscopy

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

Structure the Research Questions

A wide range of questions was proposed for research. The questions focussed on interventions rather than diagnosis or prognosis. All proposed questions were reviewed on the basis of their purpose, scope, and clinical importance to the target audience and were structured according to the PICO (populations, interventions, comparisons, outcomes) formulation.

The Guidelines for all three components are designed to answer the question as to how frequently patients require surveillance colonoscopy to achieve maximal protection against the development of colorectal cancer (CRC), in their individual circumstances.

The clinical questions asked:

- What are the appropriate intervals between colonoscopies after polypectomy?
- What are the appropriate intervals between colonoscopies after CRC resection?
- What are the appropriate intervals between colonoscopies in patients diagnosed with inflammatory bowel disease?

Develop a Search Strategy

Each research question was submitted to a search strategy based on the PICO formulation.

Most searches were directed to colorectal cancer as a generic base. Searches were limited or widened as necessary, but all maintained the PICO structure. Keywords were selected during the PICO process. Further sources for keywords or Medical Subject Headings (MESH) and subject terms were derived from evidence-based material, systematically reviewed articles, and appropriately relevant literature. A single systematic search strategy was derived from these terms and applied to all included electronic databases.

Search the Literature

The National Health and Medical Research Council (NHMRC) specifies that clinical practice guidelines should be based on systematic identification and synthesis of the best available scientific evidence. All literature searches were conducted systematically using electronic databases concluding 31 December 2009.

The literature review process of this document includes a systematic search of PubMed-Medline, EMBASE, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Cochrane to select published guidelines, systematic reviews, and primary studies assessing the use of colonoscopy for surveillance after endoscopic resection of colonic polyps and for surveillance after curative-intent resection of CRC for the years 2003–2009 and inflammatory bowel disease for the years 1990–2009. An additional search was done for the years 1990–2002 on surveillance after endoscopic resection of colonic polyps and for surveillance after curative-intent resection of CRC to add relevant articles which were not included in the literature included in the Clinical Practice Guidelines for the prevention, early detection, and management of CRC, approved by the NHMRC in 2005.

See Appendix A in the original guideline document for specific search terms, dates searched, and search results.

For each search, the following details were provided in topic- or question-specific reports (available on request from the Cancer Council Australia):

- Electronic databases searched
- Terms used to search the databases
- Search inclusion or exclusion criteria
- Language
- Study type

Studies published before 31 December 2009 could be included in the systematic reviews. Studies published after this date could not be included in the evidence base for the recommendations but could be referred to in the text and were described in the Appendices to the topic- or question-specific reports (available on request from the Cancer Council Australia). The project team also hand-searched the reference lists of the relevant articles to identify additional articles that had not been detected through searches of the electronic databases. Bi-annual meetings of the guidelines Working Party provided a forum for discussing and sharing overlapping evidence, the discovery of unpublished literature and information from other key organisations or individuals.

#### Select, Assess, and Summarise the Literature

The literature identified by the electronic database searches was assessed for relevance to each question. The following steps were taken to select and sort the literature, with the details and results summarised in topic- or question-specific reports (available on request from the Australian Cancer Network):

1. Define the inclusion criteria:

The search was limited to English language and to the heading appearing in the title and abstract of articles. Reviews, instructive guidelines, comments, and letters are not referred to when critical analyses of the data is performed. These were used to refer the reader to further information and for comparative analyses (for example, international view of guidelines for adenoma and CRC surveillance). The literature search focussed on diagnoses of colorectal lesions and inflammatory bowel disease at the time of baseline examination and during surveillance colonoscopy. Also, in PubMed searches (dated 1 May 2010), several search strategies were combined to one single search.

No limitation on date was used when searching data bases for articles on cost effectiveness related to colonoscopy surveillance following adenoma resection, CRC resection and inflammatory bowel disease diagnosis. Studies for cost effectiveness were selected based on titles and abstracts and omitting any studies that did not deal directly with the topic (e.g., screening rather than surveillance after cancer, other cancers with CRC mentioned incidentally, treatment rather than surveillance).

2. Review titles and abstracts of retrieved citations to identify potentially relevant articles.
3. Obtain the full text of potentially relevant articles.
4. Determine whether the study described in each collected article met the pre-defined inclusion criteria.
5. Determine whether systematic reviews accounted for all preceding literature.
6. Prepare folders to file searches, background papers, and reviewed articles for each question addressed.

Two independent assessors assessed the quality of each of the included studies according to pre-defined criteria for the various study types. Any disagreements were adjudicated by a third reviewer. The quality criteria were:

- *Randomised controlled trials*: blinding, allocation concealment, follow up, and intention-to-treat analysis and mode of randomisation
- *Systematic reviews*: search strategy used, the inclusion criteria and their application, study quality assessment, summary descriptive tables, pooling methods, and examination of heterogeneity
- *Quasi-randomised and cohort studies*: subject selection, group comparability, comparability of outcome measurement, blinding, and completeness of follow up

Criteria for the critical appraisal process are available on the [Cancer Council Australia website](#) .

## Economic Evidence

Searches were conducted using Medline and EMBASE databases, covering the period 1994–2010. In addition, the reference lists of retrieved articles were hand searched. Economic evaluation literature that pre-dates 1994 was considered to be of limited relevance because of changes in technology, cost structures, and management practices. The searches were undertaken in three areas:

- Colonoscopic surveillance following surgical resection for CRC
  - Key words included colorectal cancer, colon cancer, colorectal neoplasms, colorectal surgery, surveillance, colonoscopy, follow-up, cost-effectiveness, cost-benefit analysis, health economics, costs, and cost analysis
- Colonoscopic surveillance in people who have had adenomas removed
  - Key words included adenoma, colonic neoplasms, intestinal polyps, colorectal adenoma, colon adenoma, surveillance, colonoscopy, follow-up, health economics, cost-effectiveness, costs, and cost analysis
- Colonoscopic surveillance in people with ulcerative colitis
  - Key words included ulcerative colitis, colonoscopy, surveillance, follow-up, health economics, cost-benefit analysis, cost-effectiveness, costs, and cost analysis

Articles were included if they were judged to be cost analyses or economic evaluations, that is, if they involved comparison of alternative interventions in terms of costs and consequences. Studies that were reviews of economic evaluations and studies that combined costs of screening and surveillance were not included.

## Number of Source Documents

Not stated

## Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

Designations of Levels of Evidence for Intervention Research Questions (National Health and Medical Research Council [NHMRC], 2009)

Level	Intervention
I	A systematic review of level II studies
II	A randomised controlled trial
III-1	A pseudo-randomised controlled trial (i.e., alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"><li>• Non-randomised, experimental trial</li><li>• Cohort study</li><li>• Case-control study</li><li>• Interrupted time series with a control group</li></ul>
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"><li>• Historical control study</li><li>• Two or more single-arm studies</li><li>• Interrupted time series without a parallel control group</li></ul>
IV	Case series with either post-test or pre-test/post-test outcomes

Level	Intervention
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## Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

Select, Assess, and Summarise the Literature

Summaries of the studies were tabulated in PICO (populations, interventions, comparisons, outcomes) format and the relevant data extracted and summarised in tables. The data extraction was checked by a second assessor. These tables of study characteristics and evidence are included in the topic- or question-specific reports (available on request from the Cancer Council Australia). The reports also contain lists of collected studies that did not meet the inclusion criteria and the reason for their exclusion.

Critical Appraisal and Summary

For each clinical question, the included studies and their results were summarised in a template (Template 1 in the Handbook [see the "Availability of Companion Documents" field]). Each study was submitted to further critical appraisal. The level of the evidence, the quality of evidence as determined above, the size of effect, and relevance of the evidence of each included study was documented.

Details of the templates, rating systems, and criteria for the critical appraisal process are available on the [Cancer Council Australia website](#) . Levels of evidence are outlined in the "Rating Scheme for the Strength of the Evidence" field.

Assess the Body of Evidence

The body of literature was assessed by each expert sub-committee in regard to the volume of the evidence, its consistency, clinical impact, generalisability, and applicability. These aspects were graded and documented in a second template (Template 2 in the Handbook [see the "Availability of Companion Documents" field]).

## Methods Used to Formulate the Recommendations

Expert Consensus

## Description of Methods Used to Formulate the Recommendations

The Cancer Council Australia (CCA) was commissioned by the Screening Section of the Department of Health and Ageing (DoHA) to review sections of several chapters of the *Clinical Practice Guidelines for the prevention, early detection and management of colorectal cancer* approved by the NHMRC in 2005 with a specific focus on colonoscopic surveillance. Cancer Council Australia then submitted a proposal to the National Health and Medical Research Council (NHMRC) to develop the *Clinical Practice Guidelines for Surveillance Colonoscopy - in adenoma follow-up, following curative resection of colorectal cancer, and for cancer surveillance in inflammatory bowel disease*.

A Working Party composed of clinical specialists, a consumer and a Project Officer carried out the work. The Project Officer conducted literature searches, assisted in the critical evaluation of the literature and extracted the relevant data.

The development program was designed to meet the standards of scientific rigour required by the NHMRC guideline development process, which is the subject of a series of handbooks on the main stages involved in the development of clinical practice guidelines. The eight NHMRC handbooks have been condensed previously into a single volume—Development of clinical practice guidelines for the management of cutaneous melanoma and melanoma in special sites: a handbook for chapter leaders and expert working groups—which outlines the major steps and expectations involved in developing guidelines and provides a clear path for everyone involved in the project. This handbook provides the definitions and protocols for developing research questions and search strategies, conducting searches and critical appraisal, summarising, and assessing the relevant literature and, finally, formulating the recommendations. It includes checklists and templates created to meet NHMRC requirements and designated standards of quality and process (see the "Availability of Companion Documents" field for an updated version of this handbook).

At its initial meetings the Guidelines Working Party prepared a table of topics and developed questions to address identified clinical needs. The questions were identified with the specific focus of the revision being the role of surveillance colonoscopy in chapters 8, 9, 17, and 23 of the *Clinical Practice Guidelines for the prevention, early detection, and management of colorectal cancer 2005* and also in a new chapter dealing with surveillance colonoscopy in the management of patients with inflammatory bowel disease. Subcommittees of the Guidelines Working Party were formed to address topics in their areas of expertise.

#### Steps in Preparing the Guideline

A clear strategy was developed for every topic and each expert group followed the appropriate steps in preparing the guidelines. While each subcommittee received significant assistance from the Project Officer skilled in methodology, the subcommittees themselves oversaw the synthesis of the evidence and formulation of the recommendations for their topics.

The strategic steps followed are outlined below:

1. Structure the research questions.
2. Develop a search strategy.
3. Search the literature.
4. Select, assess, and summarise the literature.
5. Critically appraise and summarise each selected article.
6. Assess the body of evidence and formulate recommendations.

#### Assess the Body of Evidence and Formulate the Recommendations

Following grading of the body of evidence, expert sub-committees were asked to formulate a recommendation that related to the summarised body of evidence.

Each recommendation was assigned a grade by the expert working group taking into account the volume, consistency, generalisability, applicability, and clinical impact of the body of evidence supporting each recommendation (see the "Rating Scheme for the Strength of the Recommendations" field).

When no Level I or II evidence was available but there was consensus among the working party members, recommended best practice points have been provided, and can be identified throughout the original guideline with the following: Practice Point (PP).

#### Review of the Chapters

The body of evidence and recommendations for each chapter were reviewed by the Guidelines Working Party and final recommendations agreed to, based on the evidence.

## Rating Scheme for the Strength of the Recommendations

#### Grades of Recommendation

Grade of Recommendation	Description
A	Body of evidence can be trusted to guide practice.
B	Body of evidence can be trusted to guide practice in most situations.
C	Body of evidence provides some support for recommendations but care should be taken in its application.
D	Body of evidence is weak and recommendation must be applied with caution.

Practice Point: When no Level I or II evidence was available but there was consensus among the working party members, recommended best practice points have been provided, and can be identified throughout the original guideline with the following: Practice Point (PP).

## Cost Analysis

#### Role of Economic Evidence in the Development of Guidelines

Two main areas where economic evidence is important in clinical guideline development have been identified by the National Health and Medical Research Council (NHMRC) publication *How to compare the costs and benefits: evaluation of the economic evidence*:

- Determination of the most cost-effective treatment alternatives
- Determination of whether a proposed clinical practice guideline is cost-effective

In the development of these guidelines, the relevant economic evidence was identified and reviewed and economic analyses were performed. There was limited Australian economic evidence for the costs and cost-effectiveness of alternatives for colonoscopy surveillance. However, a search of the international literature was undertaken and the studies identified were reviewed and summarised (see the "Description of Methods Used to Collect/Select the Evidence" field). It is important to note that differences in cost structures and reimbursement arrangements mean that the international literature may be of limited relevance to Australia. Differences in the surveillance strategies compared may also limit the value of the economic evidence.

The NHMRC methodology for grading economic evidence has not been applied in reviewing this literature. However, the economic information has been summarised and presented in chapter 7 of the original guideline document.

See Appendix 4 in the full version of the original guideline document for additional details on the methods of economic evaluation of surveillance colonoscopies.

## Method of Guideline Validation

External Peer Review

Internal Peer Review

## Description of Method of Guideline Validation

A complete draft of the guidelines was sent out for public consultation in Australia from the period of 21 May to 21 June 2011. The consultation process included soliciting public review of the document through advertisement in a national newspaper, and alerting professional societies and groups and sponsors.

All feedback on the draft received during the consultation period in Australia was reviewed by the Guidelines Working Party. Subsequent changes to the draft were agreed by consensus, based on consideration of the evidence. A final independent review of experts in their fields was conducted before the final draft was submitted to National Health and Medical Research Council (NHMRC).

These guidelines were approved by the Chief Executive Officer of the NHMRC on 8 December 2011, under Section 14A of the National Health and Medical Research Council Act 1992.

## Evidence Supporting the Recommendations

### Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

Appropriate use of surveillance colonoscopy in adenoma follow-up, following curative resection of colorectal cancer (CRC), and for cancer surveillance in inflammatory bowel disease, which may lead to reduced incidence of and mortality from CRC

## Potential Harms

- Colonoscopy, with or without polypectomy, is an invasive procedure with a small but not insignificant risk of major complications, either from perforation (with polypectomy: 2%; without polypectomy: 0.06%), or major haemorrhage post-polypectomy (0.2%-10%), depending on size of lesion. Surveillance colonoscopies also place an important burden on endoscopy services. In the United States, 22% of all colonoscopies in patients over 55 years are performed for surveillance purposes. For these reasons, surveillance colonoscopy should be targeted at those who are most likely to benefit and at the minimum frequency required to provide adequate protection against the development of cancer.
- The literature identifies a range of complications and adverse events associated with colonoscopy. One Australian study investigated the rates of these complications. The authors conducted an audit in three teaching hospitals in Western Australia from September 1989 to December 1999. The main complications identified were post-colonoscopy bleeding and post-colonoscopy perforation of the bowel. The rates of bleeding and perforation were found to be 0.21% and 0.1% respectively. Other complications included abdominal pain, nausea/vomiting, excess sedation, cardiovascular complications, cerebrovascular complications and pulmonary aspiration. The death rate associated with colonoscopy was 0.01%.
- Following an extensive Medline database search (published from 2000 onwards), researchers found that the frequency of perforation is 1 in 1400 for all colonoscopies and 1 in 1000 for therapeutic colonoscopies. Advanced age, female sex, the presence of multiple co-morbidities, diverticular disease, and bowel obstruction have been shown to increase the risk of perforation. Rare complications include rupture of the spleen and acute appendicitis. These uncommon or rare procedural complications need to be balanced against the risks of not performing colonoscopy in each of the three clinical situations addressed by these guidelines (namely post-cancer resection, post-adenoma removal and in chronic inflammatory bowel disease). In each of these clinical scenarios, the patient is at above-average risk in their lifetime of developing colorectal cancer (CRC) if surveillance colonoscopy is not repeated. While this risk (of developing CRC) differs amongst patients in each of the three different clinical situations (and even between patients with differing prior adenoma findings, e.g. one or two small adenomas versus multiple villous adenomas more than 1 cm in size) and may be difficult to accurately quantify for a given individual, it is in each scenario more than 1 in 17 by age 75 for males and more than 1 in 27 by age 75 for females.
- Like most other diagnostic tests, colonoscopy has a false negative rate for detection of CRC and adenomas. This needs to be taken into consideration when decisions are made about the choice and timing of surveillance procedures. While the overall sensitivity for CRC is 95%, the available literature suggests that cancer miss rates are higher in the proximal colon than elsewhere in the large bowel.
- Colonoscopy is generally accepted as a useful and non-threatening procedure. It is still, however, regarded with some suspicion and promotes anxiety in a body of people undergoing the procedure.

## Qualifying Statements

### Qualifying Statements

- This document is a general guide to appropriate practice, to be followed subject to the clinician's judgment and the patient's preference in each individual case. The guidelines are designed to provide information to assist in decision-making. They are based on the best evidence available at time of compilation. The guidelines are not meant to be prescriptive.
- As guidelines, the recommendations cannot be applied rigidly to each and every patient. Nevertheless, this up-to-date, evidence-based literature review may help colonoscopists to better manage not only their patients, but also their colonoscopy waiting lists and balance the demands of groups of patients with different procedural indications. Frequent surveillance colonoscopy, repeated earlier than recommended by guidelines, should not be seen as an acceptable substitute for high-quality colonoscopy. It should also be remembered, as evidenced by the Quality Working Group's comprehensive report, that appropriately timed surveillance colonoscopy represents only one step in the overall pathway of quality colonoscopy delivery.

## Implementation of the Guideline

### Description of Implementation Strategy

#### Dissemination and Implementation

Cancer Council Australia took the lead in disseminating the guidelines in Australia. This included a campaign to raise awareness of the new

guidelines that incorporated organised media coverage through multiple outlets and an official launch. Cancer Council Australia distributed the Guidelines directly to relevant professional and other interested groups and through meetings, national conferences, and other continuing medical education events. Cancer Council Australia also uploaded the Guidelines to its [Cancer Guideline portal](#), which is a website using wiki technology. The link to the Cancer Guideline Portal is available from Cancer Council Australia's website where viewers visiting the website for guidelines will be encouraged to access the wiki site also.

A significant effort has been made to have the Guidelines introduced to senior undergraduate medical students via Cancer Council Australia's Oncology Education Committee, which has representatives from all the medical schools around Australia. Use of the Guidelines as part of core curriculum in specialty exams will be encouraged as well as the encouragement of the relevant learned Colleges (surgeons, radiation oncologists, and pathologists), to support the Guidelines and to foster their integration into hospital and community practice through resident and registrar education activities.

The scope of implementation activities depends on the availability of funding. It is recognised that a planned approach is necessary to overcome specific barriers to implementation in particular settings and to identify appropriate incentives to encourage uptake of guideline recommendations. Implementation of the Guidelines requires a combination of effective strategies and may include further continuing medical education initiatives and interactive learning, the development and promotion of computer-assisted decision aids and electronic decision-support systems, and the creation of audit and other clinical tools.

## Implementation Tools

Audit Criteria/Indicators

Clinical Algorithm

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

Getting Better

Living with Illness

Staying Healthy

### IOM Domain

Effectiveness

Patient-centeredness

## Identifying Information and Availability

### Bibliographic Source(s)

Cancer Council Australia Colonoscopy Surveillance Working Party. Clinical practice guidelines for surveillance colonoscopy “in adenoma follow-up; following curative resection of colorectal cancer; and for cancer surveillance in inflammatory bowel disease. Sydney (Australia):

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2011 Dec

## Guideline Developer(s)

Cancer Council Australia - Disease Specific Society

## Source(s) of Funding

This project was partially funded by the Australian Government Department of Health and Ageing under the National Bowel Cancer Screening Program.

## Guideline Committee

Cancer Council Australia Colonoscopy Surveillance Working Party

## Composition of Group That Authored the Guideline

*Working Party Members:* Dr Cameron Bell (*Chair*), Gastroenterologist, Royal North Shore Hospital, Director, Bowel Cancer Australia, Sydney NSW; A/Professor Terry Bolin, Gastroenterologist, A/Professor Medicine UNSW, Emeritus Consultant, Prince of Wales Hospital, President, Gut Foundation, Sydney NSW; Dr Andrew Clouston, Anatomical Pathologist, Envoi Specialist Pathologists, Brisbane QLD; Dr William Connell, Gastroenterologist, Chairman, Gastroenterological Society of Australia IBD section, Melbourne VIC; Dr Katie Ellard, Gastroenterologist, Royal North Shore Hospital, Sydney NSW; Professor James Kench (NSW), Anatomical Pathologist, Royal Prince Alfred Hospital, Sydney NSW; Dr Orly Lacham Kaplan, Project Officer, Working Party, Melbourne VIC; Dr Andrew Luck, Colorectal surgeon, President, Colorectal Surgical Society of Australia and New Zealand, Adelaide SA; Professor Finlay Macrae, Gastroenterologist, Royal Melbourne Hospital, Melbourne VIC; Professor Ian Olver AM, Convenor, Working Party/CEO, Cancer Council Australia, Sydney NSW; Professor Cameron Platell, Colorectal surgeon, Winthrop Professor of Surgery, University of Western Australia, Perth WA; Emeritus Professor Tom Reeve AC CBE, Convenor Working Party until 2 July 2010; A/Professor James St John AM, Gastroenterologist, Honorary Senior Associate, Cancer Council Victoria, Chair, Quality Working Group, National Bowel Cancer Screening Program, Melbourne VIC; Mr John Stubbs, Consumer, Executive Officer, Cancer Voices Australia, Sydney NSW; Ms Christine Vuletich, Manager, Clinical Guidelines Network, Cancer Council Australia, Sydney NSW

## Financial Disclosures/Conflicts of Interest

### Conflict of Interest Register and Management for Working Party Members

Working Party Members were asked to declare in writing any interests relevant to the guideline development, prior to commencement. Members were asked to update their information if they became aware of any changes to their interests.

All declarations were added to a register of interests as listed below. The register was made available to the Working Party throughout the development of the guideline, allowing members to take any potential conflicts of interest into consideration during discussions, decision making and formulation of recommendations.

If Working Party Members were identified as having a significant real or perceived conflict of interest, the Chair could decide that the member either leave the discussion whilst the specific area they were conflicted in was discussed or the member could remain present but not participate in

the discussion, or decision making on the specific area where they were conflicted. There were no instances where this occurred during the development of this guideline.

See Appendix 3 in the original guideline document for declarations of conflict of interest for Working Party Members.

## Guideline Status

This is the current release of the guideline.

## Guideline Availability

Electronic copies: Available from the [Cancer Council Australia Web site](#) .

## Availability of Companion Documents

The following are available:

- Cancer Council Australia Colonoscopy Surveillance Working Party. Clinical practice guidelines for surveillance colonoscopy – in adenoma follow-up; following curative resection of colorectal cancer; and for cancer surveillance in inflammatory bowel disease. Summary of recommendations. Sydney (Australia): Cancer Council Australia; 2011 Dec. Electronic copies: Available from the [Cancer Council Australia Web site](#) .
- Development of clinical practice guidelines using Cancer Council Australia's cancer guidelines wiki. Handbook 2014 for section authors and the guideline working party. Clinical Guidelines Network Cancer Council Australia. Sydney (Australia): Cancer Council Australia; 2014. 57 p. Electronic copies: Available in Portable Document Format (PDF) from the [Cancer Council Australia Web site](#) .

In addition, performance indicators are available in tables throughout the [original guideline document](#) .

## Patient Resources

None available

## NGC Status

This NGC summary was completed by ECRI Institute on April 14, 2014. The information was verified by the guideline developer on May 4, 2014.

## Copyright Statement

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